REMARKS

The final Office Action dated May 16, 2007 has been carefully reviewed and the following remarks are made in response thereto. Claims 1-15 are pending in the application and claims 1-11 are under examination. In view of the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

I. Rejections under 35 U.S.C. §112, 1st paragraph

Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The Examiner maintains that the specification as filed fails to convey to one of ordinary skill in the art that the inventors were in possession of the claimed invention. While the Examiner agrees that the promoters used in constructs cOMT1700 and cOMT667 exhibit vascular tissue specific promoter activity, she believes that the identity of the promoter sequence used in cOMT667 is unclear. The Examiner further explains that it is unknown whether the promoter sequence used in cOMT667, which has promoter activity, is contained within SEQ ID NO: 113 in light of Applicants' statements that SEQ ID NO: 12 was a portion of SEQ ID NO: 113 and that it was 98.9% identical to residues within SEQ ID NO: 113 (Office Action, pg. 3-4). From these arguments, the Examiner concludes that there is only a single example of a fragment of SEQ ID NO: 113 that has promoter activity and thus, the specification fails to disclose a representative number of species of the claimed genus by their complete structure and other identifying characteristics.

Applicants respectfully disagree with the Examiner's reasoning to support her rejection of claims 1-11. The specification as filed indicates that SEQ ID NO: 12 is 98.9% identical to the promoter comprising sequence of SEQ ID NO: 113 (nucleotides 1019-1676) (page 7, line 17-19 of the specification). In the response to the restriction requirement dated September 1, 2006, Applicants stated that "The current invention is drawn to a cOMT promoter sequence. SEQ ID NOS. 12 and 60 also contain portions of the cOMT promoter." Applicants further stated that "SEQ ID NO: 12 is a portion of the longer SEQ ID NO: 113 (See positions 1019-1675) .... As the three sequences contain extensive identity, Applicants believe the search and examination of these sequences can be made without serious burden." (see page 2 of the response dated 9/1/2006). The statements made by Applicants in the response to the restriction requirement and

the description of SEQ ID NO: 12 in the specification accurately portrayed the relationship of SEQ ID NO: 12 to SEQ ID NO: 113 and were not contradictory as the Examiner believes. Because SEQ ID NO: 12 is 98.9% identical to the promoter region of SEQ ID NO: 113 (see Figures 1 and 2), it would be considered to be a "portion" of this promoter region with extensive identity to SEQ ID NO: 113. It is clear from the specification that the promoter sequence contained in cOMT667 is SEQ ID NO: 12 (see page 8, lines 11-15, Figure 3 description). Therefore, the promoter sequence in cOMT667 (SEQ ID NO:12) is considered to be a portion of the promoter region of SEQ ID NO: 113, both of which show promoter activity (see Examples 2 and 3, Figure 3-5).

The instant specification discloses two examples of cOMT promoter sequences (used in constructs cOMT 1700 and cOMT 667), which when transfected into plant cells show vascular tissue specific promoter activity (see Examples 2 and 3, Figures 3-5). Both of these promoter sequences are contained within SEQ ID NO: 113 or have 98.9% identity with a portion of SEQ ID NO: 113, which is the sequence of the *Eucalyptus grandis* cOMT gene and promoter (Figure 2). The promoter sequence used in the cOMT 1700 is the 5' UTR of the *Eucalyptus grandis* cOMT gene (bp 1-1643), which encompasses the promoter region of SEQ ID NO: 113 identified by bold type in Figure 2. The promoter sequence used in the cOMT 667 is SEQ ID NO: 12, which is 98.9% identical to the promoter region in SEQ ID NO: 113. Both of these promoter sequences contain *cis* elements that are thought to be important for vascular specific promoter activity (see page 7, lines 15-17 of specification). The *cis* elements or motifs are underlined in the sequence in Figure 1 (SEQ ID NO: 12). A comparison between these identified motifs in SEQ ID NO: 12 and the promoter region of SEQ ID NO: 113 bolded in Figure 2 shows that the base pairs corresponding to these *cis* elements are identical between the two sequences.

In addition to these two working examples, Applicants direct the Examiner's attention to U.S. provisional application 60/425,087, filed November 8, 2002, to which this application claims priority and incorporates by reference (see page 1, lines 12-13). Applicants respectfully remind the Examiner that "information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed"(see MPEP 2163.07 (b)). This provisional application discloses SEQ ID NOs 2-6, which contain portions of the *E. grandis* promoter region identified in Figure 2 of the present application. SEQ ID NO: 2 of the provisional application is 543 base pairs in length and

100% identical to bp 1110-1643 of SEQ ID NO: 113. SEQ ID NOs 3-6 all have 3' ends that correspond to base pair 1643 of SEQ ID NO: 113, but are progressively shorter at the 5' end (SEQ ID NOs 3-6 are 485, 306, 293, and 119 base pairs in length, respectively). All of these promoter sequences demonstrated vascular tissue specific promoter activity when transfected into plant cells (see Example 2 and Figure 10 in provisional application 60/425,087). Furthermore, all of these promoter fragments contain two or more of the *cis* elements or motifs disclosed in the present application for SEQ ID NOs: 12 and 113 (see Figures 2-6, and 9 in provisional application 60/425,087). These data show that fragments of the *E. grandis* promoter smaller than SEQ ID NO:12 also demonstrate vascular specific promoter activity and all of the functional promoter sequences contain at least two of the conserved *cis* elements. Applicants submit that the above-identified relevant portions of provisional application 60/425,087, the present application's priority document, further support Applicants' position that the present application contained an adequate written description at the time of filing.

The written description requirement is satisfied when a patent specification describes the claimed invention in sufficient detail to convey to one skilled in the art that the inventor had possession of the claimed invention as of the application filing date (see MPEP 2163, Section I.) An applicant may show possession of the invention by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics (MPEP 2163, Section II, A. 3a.). The guidelines in the MPEP go on to state that for biomolecules "examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession." Furthermore, the Federal Circuit has held that there is no per se rule that requires an invention involving a biological macromolecule to contain a recitation of known structure to meet the written description requirement. *See Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006). Applicants remind the Examiner that the independent claims are limited to a promoter region contained within a specific sequence (SEQ ID NO: 113) or limited to a specific sequence (SEQ ID NOs: 12 and 60) or specific nucleotides within those sequences that are

disclosed in the present application. The structure of these specific promoter sequences as well as the identity of several *cis* motifs that are common to the functional promoters are disclosed within the instant specification. Moreover, Applicants have demonstrated the function of several promoters with these structural elements (bp 1-1643 of SEQ ID NO: 113, SEQ ID NO: 12 in Examples 2 and 3 of the instant specification, and several fragments of the promoter region of SEQ ID NO: 113 in Example 2 of U.S. provisional application 60/425,087, which was incorporated by reference as of the filing date). Given this disclosure, one of ordinary skill in the art would be able to determine appropriate functional promoter sequences and transform plants with the methods disclosed in the application. In view of these comments, Applicants hereby submit that the claimed invention is adequately described and meets the requirements of 35 U.S.C. §112, first paragraph.

The Examiner maintains that with respect to claim 2, that the specification fails to disclose any sequences that have the recited homology or are x-mers (e.g. 20-mer, 40-mer, etc.) of SEQ ID NOs: 12, 60, 113 or portions thereof with vascular specific promoter activity. The Examiner refers to MPEP section I A which states that " the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function." Applicants respectfully disagree with the Examiner's assertion that there is no correlation of structure with the stated function. Several disclosed sequences with conserved *cis* element motifs were shown to have the vascular specific promoter function. One of ordinary skill in the art provided with the disclosed sequences and methods in instant specification could determine functional promoter sequences with the percent homologies recited in claim 2 as well as x-mers and complementary sequences that would hybridize under stringent conditions to SEQ ID NOs: 12, 60, and 113.

Applicants direct the Examiner's attention to the "Revised Interim Written Description Guidelines Training Materials" posted on the USPTO website. In example 14 on page 53 of these guidelines, a scenario is described in which there is a pending claim directed to a protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction A → B. The specification of the application in which this claim is pending discloses an isolated protein which catalyzes the reaction A → B. The sequence of this protein is determined to be SEQ ID NO: 3. The specification also contemplates but ***does not exemplify***

variants of the protein and indicates that methods of making variants of the protein are routine in the art. Lastly, the specification teaches an assay for detecting the catalytic activity of the protein. The analysis of the scenario concludes that the specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since the variants must have the specified catalytic activity and must have at least 95% identity to the reference sequence. The single species (SEQ ID NO: 3), which was actually reduced to practice, was considered to be representative of the genus since all members of the genus were required to have a specific identity to the reference sequence and the applicant provided an assay by which sequences that possessed the required percent identity could be tested for the required catalytic activity. The conclusion of this analysis was that the disclosure provided an adequate written description for the claimed invention. Applicants note that this scenario is very similar to the issue in the instant application. Applicants have identified promoter sequences by SEQ ID NOs that have vascular specific promoter activity and have disclosed the structure of those specific sequences (see Figures 1-2 and sequence listing). Methods for testing sequences with the structural limitations recited in claim 2 (i.e. % identity, complementary sequences hybridizing under stringent conditions, and various fragments of the reference sequences) to determine if they have vascular specific promoter activity are disclosed in the application. Therefore, by virtue of the same analysis of the example scenario given in the guidelines, the disclosure of the instant specification should also be considered as providing an adequate written description of the claimed invention. In view of these arguments, Applicants respectfully request that the rejection of claims 1-11 be withdrawn.

II. Rejoinder of Claims

Since all claims are in condition for allowance, Applicants respectfully request the rejoinder of claims 12-15 as previously requested. Applicants respectfully disagree with the Examiner's assertion that only rejoinder of process claims are permitted when product claims are allowable. Claims 12-14 directed to a transgenic plant and methods for making transgenic plants contain all the limitations of the allowable product claims since the transgenic plants are transformed with the sequences and variants thereof of claims 1-11. Section 821.04 (a) of the MPEP states that "where restriction was required between independent or distinct products, or between independent or distinct processes, and all claims directed to an elected invention are

allowable, any restriction requirement between the elected invention and nonelected invention that depends from or otherwise requires all the limitations of an allowable claim should be withdrawn". In view of these comments, it is requested that claims 12-15 be rejoined to the allowable pending claims 1-11.

CONCLUSION

This reply is fully responsive to the Office Action dated May 16, 2007. In view of the above remarks, it is believed that the present set of claims are now in condition for allowance. Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a further telephonic conference would expedite any minor issues with regard to the pending claims, the Examiner is invited to call the undersigned attorney.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-1283.

Respectfully submitted,

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